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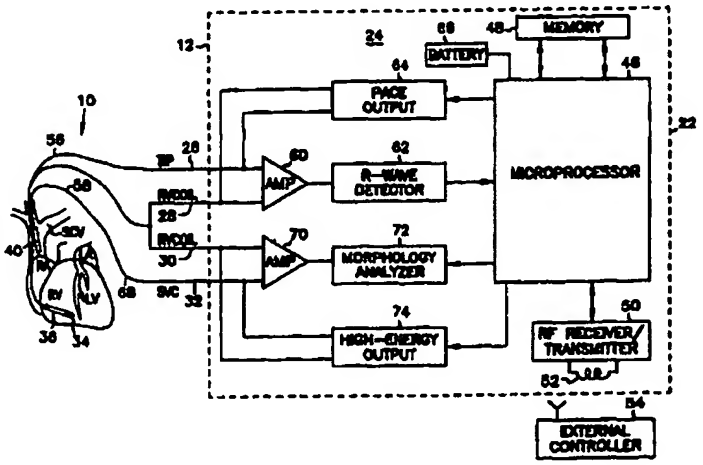

(57) Abstract

The present invention includes a defibrillation system and method for treating a heart experiencing a ventricular arrhythmia by preconditioning a region of cardiac tissue surrounding a defibrillation electrode using a plurality of high energy pacing pulses. The plurality of high energy electrical pulses are provided to the region of cardiac tissue surrounding the first defibrillation electrode to prevent aberrant ventricular contractions of the heart for a quiescent interval after the defibrillation shock has been delivered, thus increasing the probability of converting the fibrillating heart. The plurality of electrical pulses can also be provided to the region of cardiac tissue surrounding the defibrillation electrode to affect the state of coarse ventricular fibrillation complex signals, where the plurality of electrical pacing pulses affecting the state of coarse ventricular fibrillation complex signals creates or augments coarse ventricular fibrillation complex signals. The coarse ventricular fibrillation complex signals can then be used to coordinate the delivery of a defibrillation level shock.

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SYSTEM AND METHOD FOR VENTRICULAR DEFIBRILLATION

Technical Field

The present invention relates generally to implantable medical devices and in particular to the use of an implantable cardioverter defibrillator for treating arrhythmias of a patient's heart.

Background of the Invention

Cardiac arrest occurs in more than 500,000 people annually in the United States, and more than 70% of the out-of-hospitals occurrences are due to cardiac arrhythmias that are treatable with defibrillators. The most serious arrhythmia treated by a defibrillator is ventricular fibrillation. Without rapid treatment using a defibrillator, ventricular fibrillation causes complete loss of cardiac function and death within minutes.

The general mechanism of ventricular fibrillation is chaotic electrical excitation of the myocardium that results in a loss of coordinated mechanical contraction characteristic of normal heart beats. These rhythm disorders are commonly held to be a result of reentrant excitation pathways within the heart. The underlying abnormalities that lead to the mechanism are the combination of conduction block, or resistance, of cardiac excitation waves plus rapidly recurring depolarization of the membranes of the cardiac cells. This leads to rapid repetitive propagation of a single excitation wave or of multiple excitatory waves throughout the heart. If there are multiple waves, the rhythm may degrade into total loss of synchronization of cardiac fiber contraction. Without synchronized contraction, the chamber affected will not contract, and this is fatal when it occurs in the ventricles of the heart. The most common cause of these conditions, and therefore of these rhythm disorders, is cardiac ischemia or infarction as a complication of atherosclerosis. The corrective measure is to stop the rapidly occurring waves of excitation by simultaneously depolarizing most of the cardiac cells with a strong electrical shock. The cells then can simultaneously repolarizing themselves, and thus they will be back in phase with each other.

The implantable cardioverter defibrillator (ICD) is a therapeutic device that can detect ventricular tachycardia or fibrillation and automatically deliver strong electrical shocks to restore normal sinus rhythm. The ICD consists of a primary battery, a high-voltage capacitor, and sensing and control circuitry housed within a hermetically sealed titanium case. The ICD includes a transvenous lead system which is implanted into the heart of a patient.

Recognizing that there is variation in the ability of any ICD system to defibrillate at a particular instant in time is important. The spectrum of factors which may contribute to this variability are not fully understood. For example, the same setting on an ICD can fail on one attempt but be successful a few seconds later, with no obvious change in any measured variable. A need, therefore, exists to increase the probability and the efficacy of converting a ventricular fibrillation on each ICD defibrillation attempt.

Summary of the Invention

The present invention includes a defibrillator system and a method for detecting and treating ventricular arrhythmias, including ventricular fibrillation, that provides a series of high energy pacing pulses to the cardiac tissue surrounding a defibrillation electrode prior to delivering a defibrillation level shock to the heart. This series of pre-defibrillation electrical pacing pulses helps to increase the probability and the efficacy of converting a ventricular fibrillation on each defibrillation attempt by preparing the cardiac tissue for defibrillation in at least one of two ways. First, the pre-defibrillation electrical pacing pulses help to prevent aberrant ventricular contractions from occurring in the region of a defibrillation electrode shortly after a defibrillation shock has been delivered. This results in a reduced likelihood of perpetuating or reinitiate ventricular fibrillation after a defibrillation pulse has been delivered to the heart. Second, the pre-defibrillation electrical pacing pulses can affect coarse ventricular fibrillation complex signals or coarse ventricular fibrillation electrogram structures detected by an implantable cardioverter defibrillator. The coarse ventricular fibrillation complex signals are then used to coordinate the delivery of a defibrillation pulse to a heart experiencing a ventricular arrhythmia. As such, the system and method of the present invention increases the probability

and the efficacy of converting a ventricular fibrillation with a single defibrillation shock, resulting in ICDs with longer life, smaller sizes and less weight due to a more efficient use of the battery system.

The present invention includes a ventricular catheter releasably attached to an implantable housing and electronic control circuitry within the implantable housing of the defibrillator system for receiving cardiac signals through ventricular electrodes on the ventricular catheter. The ventricular catheter has a ventricular pacing electrode and a first and a second defibrillation electrode on its peripheral surface which are electrically connected to the electronic control circuitry within the implantable housing. The ventricular catheter is positioned within the heart with the ventricular pacing electrode and the first defibrillation electrode in the right ventricle chamber of the heart and the second defibrillation electrode in a right atrium chamber or a major vein leading to the right atrium chamber of the heart.

Upon detecting a ventricular arrhythmia, plurality of electrical pacing pulses are delivered to the heart. The electrical pulses are high energy pacing pulses delivered between the ventricle pacing electrode and the first defibrillation electrode. Alternatively, the electrical pulses are high energy pacing pulses delivered between the first and the second defibrillation electrodes. These electrical pacing pulses serve to precondition the cardiac tissue surrounding the first defibrillation electrode so that a subsequent defibrillation pulse delivered between the first and second defibrillation electrodes at a predetermined time after a final electrical pulse will have a higher probability of converting a ventricular arrhythmia.

In one embodiment of the present invention there is provided a system and a method of treating a heart experiencing a ventricular arrhythmia, where a region of cardiac tissue surrounding a first defibrillation electrode is preconditioned using plurality of high energy electrical pulses, including a final electrical pulse, prior to delivering a defibrillation shock. The preconditioning of the region of cardiac tissue reduces the potential of aberrant ventricular contractions from occurring in the region of cardiac tissue surrounding the first defibrillation electrode for a quiescent interval after a defibrillation shock has

been delivered. This results in a greater probability of converting a ventricular fibrillation on the first attempt.

In an alternative embodiment, the region of cardiac tissue surrounding the first defibrillation electrode is postconditioned using a plurality of electrical pacing pulses after the system has delivered a defibrillation shock to the heart. Upon detecting a ventricular fibrillation the system delivers a defibrillation pulse to the heart. At a predetermined time after delivering the defibrillation pulse, the system delivers the plurality of electrical pacing pulses to the heart. The electrical pulses are high energy pacing pulses delivered between the ventricle pacing electrode and the first defibrillation electrode. Alternatively, the electrical pulses are high energy pacing pulses delivered between the first and the second defibrillation electrodes. The postconditioning of the region of cardiac tissue reduces the potential of aberrant ventricular contractions from occurring in the region of cardiac tissue surrounding the first defibrillation electrode for a quiescent interval after the high energy pacing pulses have been delivered. This results in a greater probability of converting a ventricular fibrillation on the first attempt.

In another embodiment, the system and method of the present invention treats a heart experiencing a ventricular arrhythmia by applying a plurality of electrical pacing pulses to affect the state of coarse ventricular fibrillation complex signals. In one aspect of this present embodiment, the plurality of electrical pacing pulses are delivered to the heart to create a coarse ventricular fibrillation complex signals. Alternatively, in another aspect of this present embodiment, the plurality of electrical pacing pulses are delivered synchronously with a detected coarse ventricular fibrillation complex signal to maintain or increase the coarseness of the coarse ventricular fibrillation complex signals.

The coarse ventricular fibrillation complex signals are then used to coordinate the delivery of the defibrillation level shock, where the delivery of the defibrillation shock is coordinated to an upslope portion of a coarse ventricular fibrillation complex signals. In an alternative embodiment, the occurrence of coarse ventricular fibrillation complex signals are counted, and the delivery of the defibrillation shock is coordinated with a predetermined portion of the

upslope of a predetermined numbered occurrence of coarse ventricular fibrillation complex signals, where the predetermined numbered occurrence of coarse ventricular fibrillation complex signals is greater than or equal to 2 and less than or equal to about 9.

Brief Description of the Drawings

Figure 1 is a schematic diagram of one embodiment of a defibrillator system, including an implantable cardioverter defibrillator with a ventricular lead, implanted in a human heart from which segments have been removed to show details;

Figure 2 is a block diagram of one embodiment of the implantable cardioverter defibrillator with which the present invention may be implemented, including a diagrammatic representation of a ventricular lead placed in the heart;

Figure 3 is a waveform of a morphology signal from a heart in ventricular fibrillation (VF);

Figure 4 is a flow chart illustrating one embodiment of a mode of operation of the defibrillator system of Figure 1 in detecting and treating a ventricular arrhythmia;

Figure 5 is a waveform of a morphology signal from a heart in VF being treated by one embodiment of a method of the present invention;

Figure 6 is a flow chart illustrating one embodiment of a mode of operation of the defibrillator system of Figure 1 in detecting and treating a ventricular arrhythmia;

Figure 7 is a waveform of a morphology signal from a heart in VF being treated by one embodiment of a method of the present invention;

Figure 8 is a flow chart illustrating one embodiment of a mode of operation of the defibrillator system of Figure 1 in detecting and treating a ventricular arrhythmia;

Figure 9 is a waveform of a morphology signal from a heart in VF;

Figure 10 is a waveform of a morphology signal from a heart in VF being treated by one embodiment of a method of the present invention;

Figure 11 is a waveform of a morphology signal from a heart in VF being treated by one embodiment of a method of the present invention;

Figure 12 is a flow chart illustrating one embodiment of a mode of operation of the defibrillator system of Figure 1 in detecting and treating a ventricular arrhythmia; and

Figure 13 is a flow chart illustrating one embodiment of a mode of operation of the defibrillator system of Figure 1 in detecting and treating a ventricular arrhythmia.

Detailed Description

In the following detailed description, reference is made to the accompanying drawings which form a part hereof and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice and use the invention, and it is to be understood that other embodiments may be utilized and that electrical, logical, and structural changes may be made without departing from the spirit and scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense and the scope of the present invention is defined by the appended claims and their equivalents.

The embodiments of the present invention illustrated herein are described as being included in an implantable cardioverter defibrillator, which may include numerous pacing modes as are known in the art. The system and method of the present invention could also be implemented in an external defibrillator/monitor.

Referring now to Figures 1 and 2 of the drawings, there is shown a defibrillator system 10 including an implantable cardioverter defibrillator 12 physically and electrically coupled to a ventricular catheter 14, which the defibrillator system 10 may use in practicing the method according to the present invention. The defibrillator system 10 is implanted in a human body 16 with portions of the ventricular catheter 14 inserted into a heart 18 to detect and analyze electric cardiac signals produced by the ventricles 20 of the heart 18 and to provide electrical energy to the heart 18 under certain predetermined conditions to treat ventricular arrhythmias, including ventricular fibrillation, of the heart 18 .

A schematic of the defibrillator 12 electronics is shown in Figure 2. The system for defibrillating a heart 18 has an implantable cardioverter defibrillator 12 comprising an implantable housing 22 which contains electronic control circuitry 24. The electronic control circuitry 24 includes terminals, labeled with reference numbers 26, 28, 30 and 32, for connection to the ventricular catheter 14.

The ventricular catheter 14 is an endocardial lead, although other types could also be used within the scope of the invention. The ventricular catheter 14 is adapted to be releasably attached to the implantable housing 22 of the defibrillator system 10. The ventricular catheter 14 is shown as having a first ventricular pacing electrode 34 located at, or adjacent, the distal end of the ventricular catheter 14, which is connected electrically through a conductor provided in the ventricular catheter 14, for connection to terminal 26 and to the electronic control circuitry 24. The ventricular catheter 14 also includes a first defibrillation electrode 36 and a second defibrillation electrode 40 both connected to the electronic control circuitry 24. In one embodiment, the first defibrillation electrode 36 and the second defibrillation electrode 40 are defibrillation coil electrodes as are known in the art.

The first defibrillation electrode 36 is positioned on the ventricular catheter 14 and a distance back from the first ventricular pacing electrode 34 such that when the ventricular catheter 14 is positioned within the heart 18 the first ventricular pacing electrode 34 and the first defibrillation electrode 36 are positioned in the right ventricle 38 of the heart 18 , with the first ventricular pacing electrode 34 in an apex location within the right ventricle 38. The first defibrillation electrode 36 connects through internal conductors in the lead and is connected both to terminals 28 and 30 and to the electronic control circuitry 24. The second defibrillation electrode 40 is positioned a distance back from the first defibrillation electrode 36 such that the second defibrillation electrode 40 is in a right atrium chamber 42 or a major vein 44 leading to the right atrium chamber 42 of the heart 18 . The second defibrillation electrode 40 connects through internal conductors in the ventricular catheter 14 and is connected to terminal 32.

The defibrillator 12 is a programmable microprocessor-based system, with a microprocessor indicated by reference number 46. Microprocessor 46 operates in conjunction with a memory 48, which contains parameters for various pacing and sensing modes. Microprocessor 46 includes means for communicating with an internal controller, in the form of an RF receiver/transmitter 50. This includes a wire loop antenna 52, whereby it may receive and transmit signals to and from an external controller 54. In this manner, programming inputs can be applied to the microprocessor 46 of the defibrillator 12 after implant, and stored data on the operation of the system in response to patient needs can be read out for medical analysis.

In the defibrillator 12 of Figure 1, the first ventricle pacing electrode 34 and the first defibrillation electrode 36, connected through leads 56 and 58, are applied to a sense amplifier 60, whose output is shown connected to an R-wave detector 62. These components serve to sense and amplify the QRS wave of the heart, and apply signals indicative thereof to the microprocessor 46. Among other things, microprocessor 46 responds to the R-wave detector 62, and provides pacing signals to a pace output circuit 64, as needed according to the programmed pacing mode. Pace output circuit 64 provides output pacing signals to terminals 26 and 28, which connect as previously indicated to the first ventricular pacing electrode 34 and the first defibrillation electrode 36, for normal pacing and pacing according to the present invention. In an alternative embodiment, the pace output circuit 64 can provide output pacing signals to terminals 30 and 32 (not shown), which connects as previously indicated to the first defibrillation electrode 36 and the second defibrillation electrode 40 for delivering normal pacing and pacing according to the present invention.

The first and the second defibrillation electrodes 36 and 40, connected through leads 58 and 68, are applied to a sense amplifier 70, whose output is shown connected to a morphology analyzer 72 and the microprocessor 46. These components serve to sense, amplify and analyze the morphology of the QRS wave of the heart. Among other things, microprocessor 46 responds to the morphology analyzer 72, and provides signals to a high-energy output circuit 74 and the pace output circuit 64 to provide pacing and defibrillation level electrical

energy to the heart as needed according to the method and system of the present invention. Power to the implantable cardioverter defibrillator 12 is supplied by an electrochemical battery 66 that is housed within the implantable cardioverter defibrillator 12.

The electronic control circuitry 24 receives cardiac signals through the ventricle electrodes 34, 36 and 40, and delivers, upon detecting a ventricular arrhythmia, plurality of electrical pacing pulses to the heart and a defibrillation pulse at a predetermined time after a final electrical pulse. In the embodiment shown in Figure 1, the ventricular catheter 14 and the electronic control circuitry 24 are utilized for sensing the rate and morphology signals from the ventricular 20 activity. Unipolar and/or bipolar pacing and ventricular rate sensing can be used in conjunction with the first ventricular pacing electrode 34 and the first defibrillation electrode 36 of the ventricular catheter 14. Ventricular activity is determined by sensing for the occurrence of ventricular R-waves. The first ventricular pacing electrode 34 can be used for either unipolar rate sensing between the first ventricular pacing electrode 34 and the implantable housing 22, or bipolar rate sensing between the first ventricular pacing electrode 34 and the first defibrillation electrode 36. Ventricular morphology signals can be sensed between the first and the second defibrillation electrodes 36 and 40, where the electrodes are coupled through the sense amplifier 70 to the morphology analyzer 72 and the microprocessor 46 to assess and analyze the morphology of the sensed ventricular signals. In an alternative embodiment, it is also possible to detect unipolar cardiac morphology signals between the first defibrillation electrode 36 and the implantable housing 22. Pacing therapies (bipolar or unipolar) are delivered to the ventricles 20 of the heart 18 using these same electrodes.

The defibrillator 12 further includes a high-energy output circuit 74, which operates under the control of the microprocessor 46, as indicated. The high-energy output circuit 74 is connected to the first and second defibrillation electrode terminals 30 and 32, which connects to the first and second defibrillation electrodes 36 and 40 as previously mentioned. In this manner, defibrillation pulses can be delivered between the first defibrillation electrode 36

and the second defibrillation electrode 40 when called for by the microprocessor, and specifically the software implementation of control algorithms.

In an alternative embodiment, the implantable housing 22 of the defibrillator system 10 can be a defibrillation electrode, where the implantable housing 22 of the implantable cardioverter defibrillator 12 has an exposed electrically conductive surface that is electrically connected to the high-energy output circuit 74, such that the plurality of electrical pulses to the heart 18 are high energy pacing pulses delivered between the first ventricle pacing electrode 34 and the first defibrillation electrode 36, and the defibrillation pulse is delivered between the first defibrillation electrode 36 and the exposed electrically conductive surface of the implantable housing 22. Alternatively, defibrillation pulses can be delivered between either of the defibrillation electrodes 36 or 40 and the implantable housing 22 of the implantable defibrillator system 10, or between any combination of the two defibrillation electrodes 36 and/or 40 and the implantable housing 22 of the implantable defibrillator system 10.

Besides the lead configuration shown in Figure 1, the defibrillator system 10 supports several other lead configurations and types. For example it is possible to use ventricular epicardial rate sensing, atrial endocardial bipolar pace/sensing, ventricular endocardial bipolar pace/sensing, epicardial patches, and ancillary leads in conjunction with the implantable cardioverter defibrillator 12.

The ventricular catheter 14 is releasably attached to and are separated from the implantable cardioverter defibrillator 12 to facilitate inserting the ventricular catheter 14 into the heart 18 . The ventricular catheter 14 is inserted into the heart 18 transvenously through a cephalic or subclavian vein (not shown) to position the distal end of the ventricular catheter 14 in the apex of the right ventricular chamber 38. The proximal end of the ventricle catheter 14 is then attached to the implantable cardioverter defibrillator 12. The proximal end of the ventricular catheter 14 is adapted to seal together with the terminals 26, 28, 30 and 32 of the implantable cardioverter defibrillator 12 to thereby engage the ventricular catheter 14 leads with the electronic control circuitry 24 of the

implantable cardioverter defibrillator 12. The implantable cardioverter defibrillator 12 of the defibrillator system 10 is then positioned subcutaneously within the body 16.

Referring now to Figure 3 there is shown a schematic of an electrocardiogram of a heart experiencing ventricular fibrillation. At 80 of Figure 3 there is shown the electrocardiogram of the ventricular fibrillation prior to defibrillation treatment by a defibrillator system. As the ventricular fibrillation progresses the electrocardiogram shows an asynchronous defibrillation shock being delivered at 82 to the heart 18 . The total amount of current delivered to the heart is important for defibrillation. However, how that current is distributed throughout the heart can be even a more important factor for defibrillation. Different amounts of current flow through different parts of the heart during a shock. For shocks delivered from intracardiac electrodes, the distribution of potential gradients is highly uneven. High potential gradients occur near the defibrillation electrodes (known as "high field" areas), and low potential gradients occur in those cardiac regions distant from the defibrillation electrodes (known as "low field" areas).

For defibrillation shocks delivered through transvenous electrodes ectopic activation fronts first appear following the shock in regions exposed to the highest potential gradients generated by the shocks. These high potential gradient regions are adjacent to the defibrillation electrodes. It is suggested that defibrillation shocks delivered by a defibrillation system that fail to convert a ventricular fibrillation are due in part to these aberrant activation fronts arising from the high potential gradient regions that reinduce ventricular fibrillation shortly after a defibrillation pulse has been delivered to the heart. These ectopic activation fronts, or extra beats, are seen in Figure 3 at 84. The aberrant ventricular contractions, or beats, impinge on areas of the ventricular myocardium that the defibrillation shock has weakly effected, and are believed to contribute to reinducing and/or continuing the ventricular fibrillation 86. As a result, additional defibrillation shocks are required to restore sinus rhythm.

Referring now to Figure 4, there is shown a flow diagram of an embodiment of the method used by the defibrillator system 10 for treating a

ventricular arrhythmia of a patient's heart 18. The embodiment reduces the potential of aberrant post-defibrillation ventricular contractions, such as those seen at 89 in Figure 3, from occurring in the cardiac region surrounding the first defibrillation electrode 36 by providing preconditioning electrical energy pacing pulses that create a post-defibrillation quiescent interval of time. Initially at 100, the defibrillator system 10 utilizes the ventricular catheter 14 for sensing the ventricular cardiac signals of the heart 18 . The electronic control circuitry 24 receives either unipolar or bipolar rate and morphology cardiac signals through the ventricular electrodes 34, 36 and 40. The sensed cardiac signals are then analyzed by the electronic control circuitry 24 of the defibrillator system 10 at 102 to determine if the heart is experiencing a ventricular arrhythmia. In this context a ventricular arrhythmia can include ventricular tachyarrythmia and ventricular fibrillation.

In analyzing the cardiac signals at 102, the electronic control circuitry 24 of the defibrillator system 10 determines the occurrence and/or presence of a ventricular arrhythmias by analyzing the morphology of the R-waves detected by the defibrillator system 10 and the rate relation of the ventricular R-waves to preprogrammed ventricular rate and rate acceleration parameters.

During 102, if the heart is not experiencing a ventricular arrhythmia, the defibrillator system 10 returns to 100, via 104, to analyze the next series of sensed ventricular intervals. However, if a ventricular arrhythmia is detected at 102, the defibrillator system 10 then proceeds to 106 where the electronic control circuitry 24 of the defibrillator system 10 functions to deliver plurality of preconditioning pulses of electrical energy to the region of cardiac tissue surrounding the first defibrillation electrode 36 (the "high field" area), including a final electrical pulse delivered at 108, so that the myocardium surrounding the first defibrillation electrode 36 will be quiescent for a quiescent interval period of time following the defibrillation shock.

In the present embodiment, the pacing pulses are high energy pacing pulses delivered either between the first ventricular pacing electrode 34 and the first defibrillation electrode 36, or between the first and the second defibrillation electrodes 36 and 40. These pre-conditioning pulses function to "stun" or render

inactive the myocardium in the "high field" area surrounding the first defibrillation electrode 36 just prior to delivering a defibrillation shock so that no aberrant ventricular contractions can arise from this area for the quiescent interval period of time after the defibrillation shock has been delivered. The quiescent interval period of time created by the preconditioning pulses of electrical energy is sufficient in duration to allow the sinoatrial node, or an implanted pacemaker, to establish sinus rhythm once again.

To precondition the myocardium, the electronic control circuitry 24 of the defibrillator system 10 delivers high energy pacing pulses to the heart through the ventricular catheter 14, as previously described, where the high energy pacing pulses are delivered at a programmed voltage of between 1 - 20 volts. In an alternative embodiment, the high energy pacing pulses are delivered at an amplitude of between 5 - 20 times the diastolic threshold of the patient. The electronic control circuitry 24 of the system is also programmed to deliver the high energy pacing pulses in a sequential series of between 10 - 200 high energy pacing pluses, at a predetermined interpulse interval of between 10 - 40, 15 - 35, or 20 - 30 milliseconds, where 20 milliseconds is a suitable value.

In an alternative embodiment, the high energy pacing pulses are delivered at a programmed current level of between 0.1 - 3 amperes, where the pre-conditioning electrical energy pulses delivered between the first and the second defibrillation electrodes 36 and 40 are between 1 - 3 amperes, with 2 amperes being a suitable value, or, alternatively, where the pre-conditioning electrical energy pulses delivered between the first ventricular pacing electrode 34 and the first defibrillation electrode 36 are between 0.1 - 0.3 amperes, with 0.2 amperes being a suitable value. In an additional embodiment, the plurality of electrical pulses delivered to pre-condition the heart are cardioversion level pulses of electrical energy.

After the cardiac tissue has been preconditioned, the defibrillator system 10 at 110 delivers a defibrillation shock at a predetermined time after the final electrical pulse, where the predetermined time of delivering a defibrillation level shock is a programmable value between 10 - 200 milliseconds. However, defibrillation pulses delivered to the heart after a final electrical pulse is not

necessarily limited to this coupling time range because it is recognized that the quiescent interval of time can result from the preconditioning pulses even when the time between the final electrical pulse and the defibrillation shock is greater than 200 milliseconds. After delivering the defibrillation level shock at 110, the defibrillator system 10 returns to 100, via 112, to analyze the next series of sensed ventricular intervals.

Referring now to Figure 5, there is shown a schematic of an electrocardiogram of a heart experiencing a ventricular fibrillation treated by the present embodiment of the method and system of the invention. At 120, the electrocardiogram indicates that the heart 18 is experiencing a ventricular fibrillation. The ventricular fibrillation is detected by the electronic control circuitry 24 of the defibrillator system 10, and responds by beginning to charge both a pacing discharge capacitor associated with the pace output circuit 64, and a defibrillation discharge capacitor associated with the high-energy output circuit 74. The pacing discharge capacitor is charged to a level of approximately 100 volt at which point the pace output circuit 64 delivers, by way of example, a series of ten (10) pre-conditioning high-energy pacing pulses at 122.

The high energy pacing pulses are delivered across either the first ventricular pacing electrode 34 or the first defibrillation electrode 36 at a preset interpulse interval of 20 milliseconds. In one embodiment, the pacing capacitor of the pace output circuit 64 is not concurrently recharged during the delivery of the high energy pacing pulses. As a result, the voltage of subsequent pacing pulses delivered during treatment of a ventricular fibrillation is at or below the voltage of the pacing pulse just previously delivered. Finally, after a final electrical pulse has been delivered to the heart 18 , the defibrillator system 10 terminates the ventricular arrhythmia at 124 by delivering a cardioversion/defibrillation pulse of electrical energy through the ventricular defibrillation electrode and across the ventricular region of the heart 18 at a predetermined time after the final electrical pulse. Figure 5 indicates that as a result of preconditioning the heart 18 with the high energy pacing pulses, the potential for aberrant ventricular contractions in the "high field" area surrounding the first defibrillation electrode 36 is reduced as a quiescent interval

of time is created at 126. This quiescent interval of time allows the heart 18 to once again fall under the control of the sinoatrial-node and/or the pacemaker of the implantable defibrillator system 10 and restore sinus rhythm as seen at 128.

Referring now to Figure 6, there is shown a flow diagram of an alternative embodiment of the method used by the defibrillator system 10 for treating a ventricular arrhythmia of a patient's heart 18 . The embodiment reduces the potential of aberrant post-defibrillation ventricular contractions, such as those seen at 89 in Figure 3, from occurring in the cardiac region surrounding the first defibrillation electrode 36 by providing postconditioning electrical energy pacing pulses to a patient's heart after a defibrillation level shock has been delivered that create a post-defibrillation quiescent interval of time. Initially at 130, the defibrillator system 10 utilizes the ventricular catheter 14 for sensing the ventricular cardiac signals of the heart 18 . The electronic control circuitry 24 receives either unipolar or bipolar rate and morphology cardiac signals through the ventricular electrodes 34, 36 and 40. The sensed cardiac signals are then analyzed by the electronic control circuitry 24 of the defibrillator system 10 at 132 to determine if the heart is experiencing a ventricular arrhythmia. In this context a ventricular arrhythmia can include ventricular tachyarrythmia and ventricular fibrillation.

In analyzing the cardiac signals at 132, the electronic control circuitry 24 of the defibrillator system 10 determines the occurrence and/or presence of a ventricular arrhythmias by analyzing the morphology of the R-waves detected by the defibrillator system 10 and the rate relation of the ventricular R-waves to preprogrammed ventricular rate and rate acceleration parameters.

During 132, if the heart is not experiencing a ventricular arrhythmia, the defibrillator system 10 returns to 130, via 134, to analyze the next series of sensed ventricular intervals. However, if a ventricular arrhythmia is detected at 132, the defibrillator system 10 then proceeds to 136 where the electronic control circuitry 24 of the defibrillator system 10 functions to deliver a defibrillation level shock to the heart.

At a predetermined time after delivering the defibrillation level shock to the heart, the defibrillation system 20 delivers a plurality of postconditioning

pulses of electrical energy at 138 to the region of cardiac tissue surrounding the first defibrillation electrode 36 (the "high field" area) so that the myocardium surrounding the first defibrillation electrode 36 will be quiescent for a quiescent interval period of time following a final postconditioning pacing pulse of electrical energy. The predetermined time of delivering the plurality of postconditioning pulses of electrical energy after delivering the defibrillation level shock is a programmable value between 10 - 100 milliseconds. However, the plurality of postconditioning pulses delivered after the defibrillation level shock is not necessarily limited to this coupling time range, and predetermined times of greater than 100 milliseconds are considered to be within the scope of the invention. After delivering the final postconditioning pacing pulse of electrical energy at 138, the defibrillator system 10 returns to 130, via 140, to analyze the next series of sensed ventricular intervals.

In the present embodiment, the pacing pulses are high energy pacing pulses delivered either between the first ventricular pacing electrode 34 and the first defibrillation electrode 36, or between the first and the second defibrillation electrodes 36 and 40. These postconditioning pulses function to "stun" or render inactive the myocardium in the "high field" area surrounding the first defibrillation electrode 36 just after delivering a defibrillation shock so that no aberrant ventricular contractions can arise from this area for the quiescent interval period of time after the final postconditioning pacing pulse has been delivered. The quiescent interval period of time created by the postconditioning pulses of electrical energy is sufficient in duration to allow the sinoatrial node, or an implanted pacemaker, to establish sinus rhythm once again.

To postcondition the myocardium, the electronic control circuitry 24 of the defibrillator system 10 delivers high energy pacing pulses to the heart through the ventricular catheter 14, as previously described, where the high energy pacing pulses are delivered at a programmed voltage of between 1 - 20 volts. The electronic control circuitry 24 of the system is also programmed to deliver the high energy pacing pulses in a sequential series of between 5 - 200 high energy pacing pluses, at a predetermined interpulse interval of between 10 - 40, 15 - 25, or 20 - 30 milliseconds, where 20 milliseconds is a suitable value.

In an alternative embodiment, the high energy pacing pulses are delivered at a programmed current level of between 0.1 - 3 amperes, where the post-conditioning electrical energy pulses delivered between the first and the second defibrillation electrodes 36 and 40 are between 1 - 3 amperes, with 2 amperes being a suitable value, or, alternatively, where the post-conditioning electrical energy pulses delivered between the first ventricular pacing electrode 34 and the first defibrillation electrode 36 are between 0.1 - 0.3 amperes, with 0.2 amperes being a suitable value. In an additional embodiment, the plurality of electrical pulses delivered to post-condition the heart are cardioversion level pulses of electrical energy.

Referring now to Figure 7, there is shown a schematic of an electrocardiogram of a heart experiencing a ventricular fibrillation treated by the present embodiment of the method and system of the invention. At 142, the electrocardiogram indicates that the heart 18 is experiencing a ventricular fibrillation. The ventricular fibrillation is detected by the electronic control circuitry 24 of the defibrillator system 10, and responds by beginning to charge both a pacing discharge capacitor associated with the pace output circuit 64, and a defibrillation discharge capacitor associated with the high-energy output circuit 74.

At 144, the defibrillator system 10 delivers a cardioversion/defibrillation pulse of electrical energy through the ventricular defibrillation electrode and across the ventricular region of the heart 18. At a predetermined time after the defibrillation pulse of electrical energy is delivered to the heart, the pace output circuit 64 delivers, by way of example, a series of five (5) post-conditioning high-energy pacing pulses at 146.

The high energy pacing pulses are delivered across either the first ventricular pacing electrode 34 or the first defibrillation electrode 36 at a preset interpulse interval of 20 milliseconds. In one embodiment, the pacing capacitor of the pace output circuit 64 is not concurrently recharged during the delivery of the high energy pacing pulses. As a result, the voltage of subsequent pacing pulses delivered during treatment of a ventricular fibrillation is at or below the voltage of the pacing pulse just previously delivered.

Figure 5 indicates that as a result of postconditioning the heart 18 with the high energy pacing pulses, the potential for aberrant ventricular contractions in the "high field" area surrounding the first defibrillation electrode 36 is reduced as a quiescent interval of time is created at 148. This quiescent interval of time allows the heart 18 to once again fall under the control of the sinoatrial-node and/or the pacemaker of the implantable defibrillator system 10 and restore sinus rhythm as seen at 150.

Referring now to Figure 8 there is shown an alternative embodiment of the present invention to treat ventricular arrhythmias, including ventricular fibrillation, by providing a series of electrical pacing pulses to the cardiac tissue surrounding the first defibrillation electrode 36 prior to delivering a defibrillation level shock to the heart 18 . The present embodiment of the invention relates to the copending U.S. Patent Application Serial No. 08/513,685, filed August 11, 1995, and the copending U.S. Patent Application entitled " IMPROVED METHOD AND APPARATUS FOR TREATING CARDIAC ARRHYTHMIA USING ELECTROGRAM FEATURES", filed May 6, 1997 both of which are hereby incorporated by reference in there entirety. The present embodiment of the method and defibrillation system of the invention delivers a series of pre-defibrillation electrical pacing pulses to increase the probability and the efficacy of converting a ventricular fibrillation by preparing the cardiac tissue for defibrillation by affecting coarse ventricular fibrillation complex signals. The coarse ventricular fibrillation complex signals are then used to coordinate the delivery of a defibrillation pulse to a heart experiencing a ventricular arrhythmia, as more fully described in the aforementioned U.S. Patent Applications.

The method of the present embodiment treats a heart experiencing ventricular fibrillation by first applying a plurality of electrical pulses is to affect the state of coarse ventricular fibrillation complex signals. The term "affected", as used in conjunction with the state of coarse ventricular fibrillation complex signals, means to produce a material influence upon or alteration in the cardiac electrogram signals that are sensed during a ventricular fibrillation. In this way the plurality of electrical pacing pulses are used to affect the state of coarse ventricular fibrillation complex signals by creating coarse ventricular fibrillation

complex signals. Subsequent pacing pulses delivered after the creation of a coarse ventricular fibrillation complex signal can then be coordinated to up-slope portions of the detected coarse ventricular fibrillation signals to further coarsen the ventricular signal.

In an alternative embodiment, if coarse ventricular fibrillation complex signals are initially detected, the plurality of electrical pacing pulses are used to affect the state of coarse ventricular fibrillation complex signals by synchronizing there delivery with the coarse ventricular fibrillation complex signals to maintain or increase the coarseness of the coarse ventricular fibrillation complex signals. This is accomplished by delivering the pacing pulses during the up-slope portion of the sensed coarse ventricular fibrillation complex signal.

Referring now to Figure 8, there is shown a flow diagram of an embodiment of a method used by the defibrillator system 10 for treating a ventricular arrhythmia of a patient's heart 18 . The embodiment of the present invention utilizes preconditioning pacing pulses to create coarse ventricular fibrillation complex signals upon which the defibrillator system 10 can coordinate the delivery of a defibrillation shock. The goal in providing the preconditioning pacing pulses is to disturb, affect, and/or reset a large portion of the ventricular tissue during a ventricular fibrillation. Initially at 170, the defibrillator system 10 utilizes the ventricular catheter 14 for sensing the ventricular cardiac signals of the heart 18 . The electronic control circuitry 24 receives either unipolar or bipolar rate and morphology cardiac signals through the ventricular electrodes 34, 36 and 40. The sensed cardiac signals are then analyzed by the electronic control circuitry 24 of the defibrillator system 10 at 172 to determine if the heart 18 is experiencing a ventricular arrhythmia. In this context a ventricular arrhythmia can include ventricular tachyarrythmia and ventricular fibrillation.

In analyzing the cardiac signals at 172, the electronic control circuitry 24 of the defibrillator system 10 can determine the occurrence and/or presence of a ventricular arrhythmias by analyzing the morphology of the R-waves detected by

the defibrillator system 10 and the rate relation of the ventricular R-waves to preprogrammed ventricular rate and rate acceleration parameters.

During 172, if the heart is not experiencing a ventricular arrhythmia, the defibrillator system 10 returns to 170, via 174, to analyze the next series of sensed ventricular intervals. However, if a ventricular arrhythmia is detected at 172, the defibrillator system 10 then proceeds to 176 where the electronic control circuitry 24 of the defibrillator system 10 functions to deliver plurality of pulses of electrical energy, including a final electrical pulse delivered at 178, to the region of cardiac tissue surrounding the first defibrillation electrode 36 to precondition the heart so that coarse ventricular fibrillation complex signals are created, or pre-existing coarse ventricular fibrillation complex signals are coarsened, in the ventricular morphology signals sensed by the defibrillator system 10.

Figure 9 illustrates a morphology signal such as would be detected by the sense amplifier 70, from a first signal appearing across the first defibrillation electrode 36 and the second defibrillation electrode 40 on the ventricular catheter 14. For other types of lead systems, similar or corresponding signals would be present.

In Figure 9 Zones F1 and F2 show regions of fine ventricular fibrillation. Zones C1 and C2 show coarse ventricular fibrillation complex signals. Within complex C1, a single peak feature of the complex is indicated by reference number 200. The difference in amplitude between the amplitude extremes, 202 and 204, indicates the peak-to-peak amplitude calculation which is used as a part of the method of the invention. In the aforementioned Patent Applications the system senses and analyzes coarse ventricular fibrillation complex signals as they naturally occur during the course of a ventricular fibrillation. In contrast to this approach, the present invention delivers pacing pulses to cardiac tissue experiencing ventricular fibrillation to create or coarsen coarse ventricular fibrillation complex signals on which the defibrillator system 10 of the present invention can coordinate the delivery of a defibrillation shock to the heart 18 .

Figures 10 and 11 are examples of coarse ventricular fibrillation complex signals being created or coarsened by the preconditioning pacing pulses

delivered at step 176 of Figure 8. F3 and F4 show regions of fine ventricular fibrillation which are sensed and analyzed by the defibrillator system 10. Upon detecting a ventricular fibrillation, the defibrillator system 10 proceeds to deliver plurality of preconditioning pacing pulses. In Figure 10, four preconditioning pacing pulses are delivered to the heart 18 starting at 206. The preconditioning pacing pulses have the effect of creating a coarse ventricular fibrillation complex signal C3 by disturbing, affecting, and/or resetting a large portion of the fibrillating ventricles. The coarse ventricular fibrillation complex signal is then used to coordinate the delivery of the defibrillation shock.

In Figure 11, the detected ventricular fibrillation begins as a fine ventricular fibrillation F4. The fine ventricular fibrillation then is shown to convert to a coarse ventricular fibrillation complex signal C4. After detecting a coarse ventricular fibrillation complex signal 208, the electronic control circuitry 24 of the defibrillator system 10 delivers a first pacing pulse of a plurality of high energy pacing pulses on the up-slope portion of a subsequent coarse ventricular fibrillation complex signal after the coarse ventricular fibrillation complex signal 208. In this example, the first pacing pulse is delivered at 210. Subsequent pacing pulses 212 are then delivered during the up-slope portions of each successive coarse ventricular fibrillation complex signal.

The plurality of pacing pulses can be delivered between the first defibrillation electrode 36 and the second defibrillation electrode 40. Alternatively, the preconditioning pulses can be delivered between the first ventricular pacing electrode 34 and the first defibrillation electrode 36 or with a separate electrode, such as the implantable housing 22 of the implantable cardioverter defibrillator 12. The electrical pacing pulses delivered to the heart 18 to create or coarsen coarse ventricular fibrillation complex signals have a programmable voltage between 3 - 9 volts. Alternatively, the plurality of pacing level pulses have a programmable energy level of between 0.0001 - 0.1 Joules. To precondition the heart 18 , the defibrillator system 10 applies the plurality of electrical pulses to the region of cardiac tissue surrounding the first defibrillation electrode to affect the state of coarse ventricular fibrillation complex signals where the plurality of pacing level pulses is a programmed value between 2 -

200, and where the electrical pacing pulses are delivered sequentially at a predetermined interval of between 1 - 40 milliseconds.

Referring now to Figure 12, once coarse ventricular fibrillation complex signals have been either created or coarsened by the preconditioning pulses a programmable time duration interval is started at step 210. The system then begins to compute a Standard Amplitude of Morphology (SAM) at 212 over the programmable time duration interval for the sensed ventricular morphology signals from a first signal appearing across the electrodes of the ventricular catheter (e.g., the first defibrillation electrode and the second defibrillation electrode). In one embodiment, the SAM value is calculated by averaging a predetermined number of the largest peak-to-peak morphology signal values detected over a predetermined time interval. The predetermined time interval can be programmed within a range of 1- 10 seconds. Also, the predetermined number of the largest peak-to-peak values can be programmed within a range of 3 - 10. The SAM value for the first signal are computed based upon peak-to-peak value readings from the first morphology signals across the ventricular catheter 14 and comparing them with previously obtained samples. When such comparison shows a trend reversing, (*i.e.*, from decreasing to increasing, or from increasing to decreasing in value) for the first signal a bottom or top (*i.e.*, a peak, negative or positive) has been reached. Such peak values are then stored for each of the first signal for comparison with other peak values as part of the SAM calculation. For each peak occurring in a coarse ventricular fibrillation complex signal, the high and low values, and hence the peak-to-peak values, are calculated and stored for the first signal.

Flow then proceeds to decision block 214, where the time for the programmable time duration interval is tested. If the time interval has not passed, flow branches back via path 216 to the computation block 212, and computation detection of peaks and computation of peak-to-peak values continue. If, however, the programmable time duration interval has expired, the SAM is calculated as being the average of the five largest peak-to-peak measurements during the time interval.

Referring now to Figure 13, where the number "2" joins the flow charts of Figures 12 and 13, a programmable waiting period is then initialized at 218, and the waiting period timer is started. The waiting period timer defines the time period during which coordinated defibrillation shocks may be attempted, and after which the system will switch to asynchronous defibrillation shocks. Decision block 220 tests whether the waiting time limit programmed for coordinated defibrillation shocks has passed. If the ventricular fibrillation is not terminated by the delivery of coordinated defibrillation shocks and the time limit at decision block 220 has passed, the defibrillator system 10 delivers at least one asynchronous defibrillation shock. If not, the amplitude of the morphology signal for a present or current point detected by the ventricular catheter 14 is determined by the defibrillator system 10 at step 222.

For the morphology signal, the amplitude of the current point is compared to the previously computed value of SAM for the signal. If the signal has a peak-to-peak amplitude greater than or equal to 50% of the signal SAM, then it is identified as a Candidate Morphology Complex (CMC) for the signal, and a programmable count "n" of a signal CMC is incremented by one. The CMC count "n" is subsequently tested at step 224 and if the count value is not equal to or above the programmed number ($2 \leq n \leq 9$) control returns to path 226 and the start of the sequence. However, if the CMC count "n" is equal to or above the programmed number the system proceeds to test at step 228 whether the current point for the current point is on an upslope, *i.e.*, has a positive slope. Step 230 then tests whether the current point is at greater then 50% of the SAM value, and has a positive slope. If either of these is not met, then control branches to path 226, to repeat the loop. If both of these conditions are met, then control passes to step 232.

At step 232, the defibrillator system 10 tests whether the stored energy in the high-energy output circuit 74 has reached the pre-programmed level. If the energy level has not been reached, control passes via 226 to loop again. After the energy level has been reached at step 232, control passes to step 234, which causes the high-energy output circuit 74 to deliver the defibrillation shock.

What is Claimed is:

1. A method, comprising the acts of:

sensing signals representative of ventricular electrical activity; and

controlling the state of coarse ventricular fibrillation complexes by delivering a plurality of pacing pulses.

2. The method of claim 1, where the plurality of pacing pulses controlling the state of coarse ventricular fibrillation complexes either creates coarse ventricular fibrillation complexes, or maintains or increases the coarseness of the coarse ventricular fibrillation complexes.

3. The method of claim 1, where the coarse ventricular fibrillation complexes have an upslope portion and the plurality of pacing pulses are synchronized with the upslope portion of the coarse ventricular fibrillation complexes.

4. The method of claim 1, further including the act of delivering a defibrillation shock during the occurrence of a coarse ventricular fibrillation complex.

5. The method of claim 4, where the coarse ventricular fibrillation complexes have an upslope portion and the defibrillation level shock is delivered during the upslope portion of the coarse ventricular fibrillation complexes.

6. The method of claim 5, where the act of delivering a defibrillation shock further includes the acts of counting occurrences of coarse ventricular fibrillation complexes, and coordinating the delivery of the defibrillation shock with the upslope of a predetermined numbered occurrence of coarse ventricular fibrillation complexes, where the predetermined numbered occurrence of coarse

ventricular fibrillation complexes is greater than or equal to 2 and less than or equal to about 9.

7. The method of claim 6, where the act of counting occurrences of coarse ventricular fibrillation complexes includes sensing when the amplitude of the coarse ventricular fibrillation complex is greater than a first predetermined value with a positive slope or rate of change.

8. The method of claim 7, where the act of delivering a defibrillation shock includes timing the delivery of the shock based on when the amplitude of the coarse ventricular fibrillation complex is greater than the first predetermined value and has a positive slope or rate of change.

9. A method of claim 6, further including the act of delivering at least one asynchronous defibrillation shock if the ventricular fibrillation is not terminated by the delivery of coordinated defibrillation shocks.

10. The method of claim 1, where the number of pacing pulses is a programmed value between 2 - 200.

11. The method of claim 1, where the pacing pulses are delivered sequentially at a predetermined interval of between 1 - 40 milliseconds.

12. The method of claim 1, where the plurality of pacing pulses are delivered at a programmed voltage of between 3 - 9 volts.

13. The method of claim 1, where the plurality of pacing pulses are delivered at a programmed energy level of between 0.0001 - 0.1 Joules.

14. A method, comprising the acts of:

sensing signals representative of ventricular electrical activity;

delivering a plurality of pacing pulses during an occurrence of ventricular fibrillation, the plurality of pacing pulses being delivered sequentially at a programmed voltage; and

delivering a defibrillation shock at a predetermined time after the plurality of pacing pulses.

15. The method of claim 14, where the number of pacing pulses is a programmable value between 10 - 200.

16. The method of claim 14, where the pacing pulses are delivered sequentially at a predetermined interpulse interval of between 10 - 40 milliseconds.

17. The method of claim 14, where the pacing pulses are delivered at an amplitude of between 5 - 20 times a diastolic threshold.

18. The method of claim 14, where the pacing pulses are delivered at a programmed current level of between 0.1 - 3 amperes.

19. The method of claim 14, where the act of delivering a defibrillation shock further includes delivering the defibrillation shock at a predetermined time after the final electrical pulse, where the predetermined time is a programmable value between 10 - 200 milliseconds.

20. A system, comprising:

a ventricular catheter including a first ventricular pacing electrode and a first defibrillation electrode; and

electronic control circuitry connected to the first ventricular pacing electrode and the first defibrillation electrode, where the electronic control circuitry senses signals representative of ventricular electrical activity through the first ventricular pacing electrode and the first defibrillation electrode, and

delivers a plurality of pacing pulses through the ventricular catheter to control the state of coarse ventricular fibrillation complexes.

21. The system of claim 20, where the plurality of pacing pulses controlling the state of coarse ventricular fibrillation complexes either creates coarse ventricular fibrillation complexes, or maintains or increases the coarseness of the coarse ventricular fibrillation complexes.

22. The system of claim 20, where the coarse ventricular fibrillation complexes have an upslope portion and the plurality of pacing pulses are synchronized with the upslope portion of the coarse ventricular fibrillation complexes.

23. The system of claim 20, where the electronic control circuitry delivers a defibrillation shock through the ventricular catheter during the occurrence of a coarse ventricular fibrillation complex.

24. The system of claim 23, where the coarse ventricular fibrillation complexes have an upslope portion and the defibrillation level shock is delivered during the upslope portion of the coarse ventricular fibrillation complexes.

25. The system of claim 24, where delivering the defibrillation shock further includes counting occurrences of coarse ventricular fibrillation complexes, and coordinating the delivery of the defibrillation shock with the upslope of a predetermined numbered occurrence of coarse ventricular fibrillation complexes, where the predetermined numbered occurrence of coarse ventricular fibrillation complexes is greater than or equal to 2 and less than or equal to about 9.

26. The system of claim 25, where counting occurrences of coarse ventricular fibrillation complexes includes sensing when the amplitude of the coarse

ventricular fibrillation complex is greater than a first predetermined value with a positive slope or rate of change.

27. The system of claim 26, where delivering a defibrillation shock includes timing the delivery of the shock based on when the amplitude of the coarse ventricular fibrillation complex is greater than the first predetermined value and has a positive slope or rate of change.

28. The system of claim 25, where the electronic control circuitry delivers at least one asynchronous defibrillation shock if the ventricular fibrillation is not terminated by the delivery of coordinated defibrillation shocks.

29. The system of claim 20, where the number of pacing pulses is a programmed value between 2 - 200.

30. The system of claim 20, where the pacing pulses are delivered sequentially at a predetermined interval of between 1 - 40 milliseconds.

31. The method of claim 20, where the plurality of pacing pulses are delivered at a programmed voltage of between 3 - 9 volts.

32. The method of claim 20, where the plurality of pacing pulses are delivered at a programmed energy level of between 0.0001 - 0.1 Joules.

33. A system, comprising:

a ventricular catheter including a first ventricular pacing electrode and a first defibrillation electrode; and

electronic control circuitry connected to the first ventricular pacing electrode and the first defibrillation electrode, where the electronic control circuitry senses signals representative of ventricular electrical activity through the first ventricular pacing electrode and the first defibrillation electrode, and

delivers a plurality of pacing pulses during an occurrence of ventricular fibrillation, the plurality of pacing pulses being delivered sequentially at a programmed voltage, and delivers a defibrillation shock at a predetermined time after the plurality of pacing pulses.

34. The system of claim 33, where the number of pacing pulses is a programmable value between 10 - 200.

35. The system of claim 33, where the pacing pulses are delivered sequentially at a predetermined interpulse interval of between 10 - 40 milliseconds.

36. The system of claim 33, where the pacing pulses are delivered at a programmed voltage of between 1 - 20 volts.

37. The system of claim 33, where the pacing pulses are delivered at an amplitude of between 5 - 20 times a diastolic threshold.

38. The system of claim 33, where the pacing pulses are delivered at a programmed current level of between 0.1 - 3 amperes.

39. The system of claim 33, where the defibrillation shock is delivered at a predetermined time after the final electrical pulse, where the predetermined time is a programmable value between 10 - 200 milliseconds.

40. The system of claim 20 or 33, further including an implantable housing, where the ventricular catheter is attached to the implantable housing, and the electronic control circuitry is contained within the implantable housing.

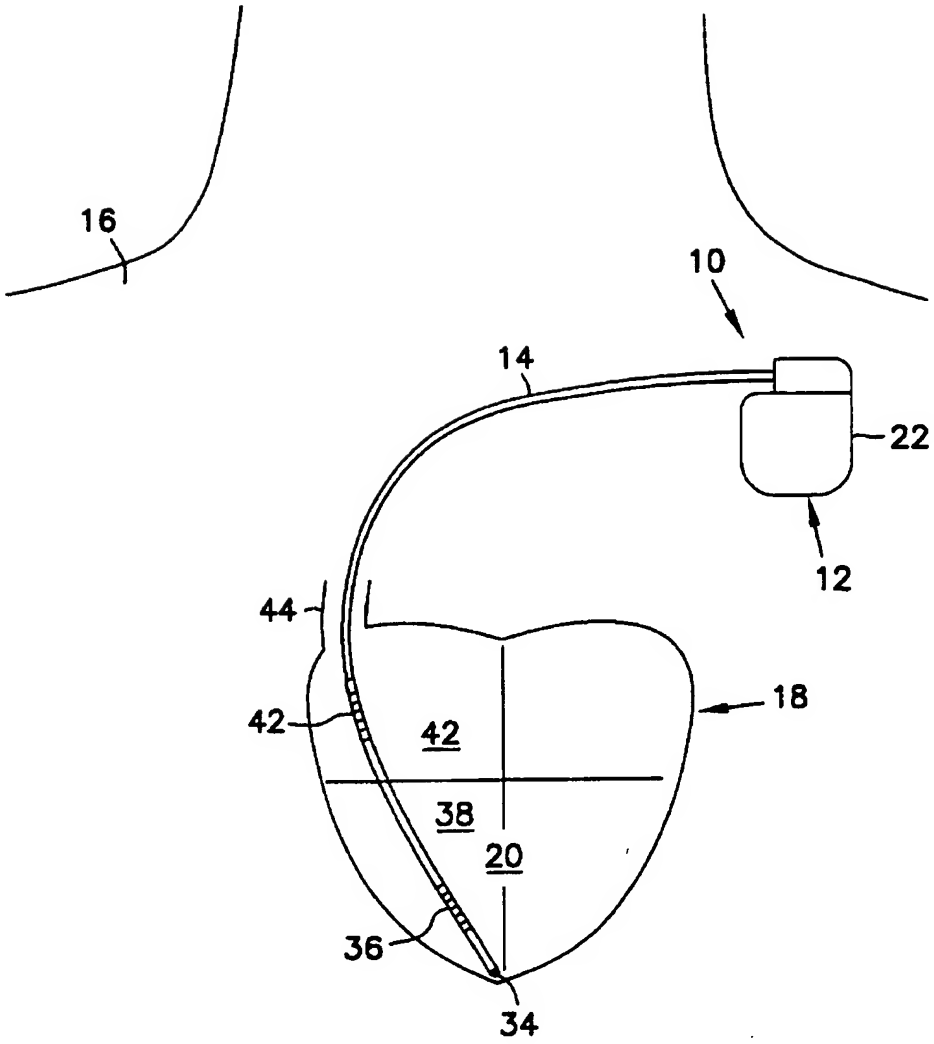

FIG. 1

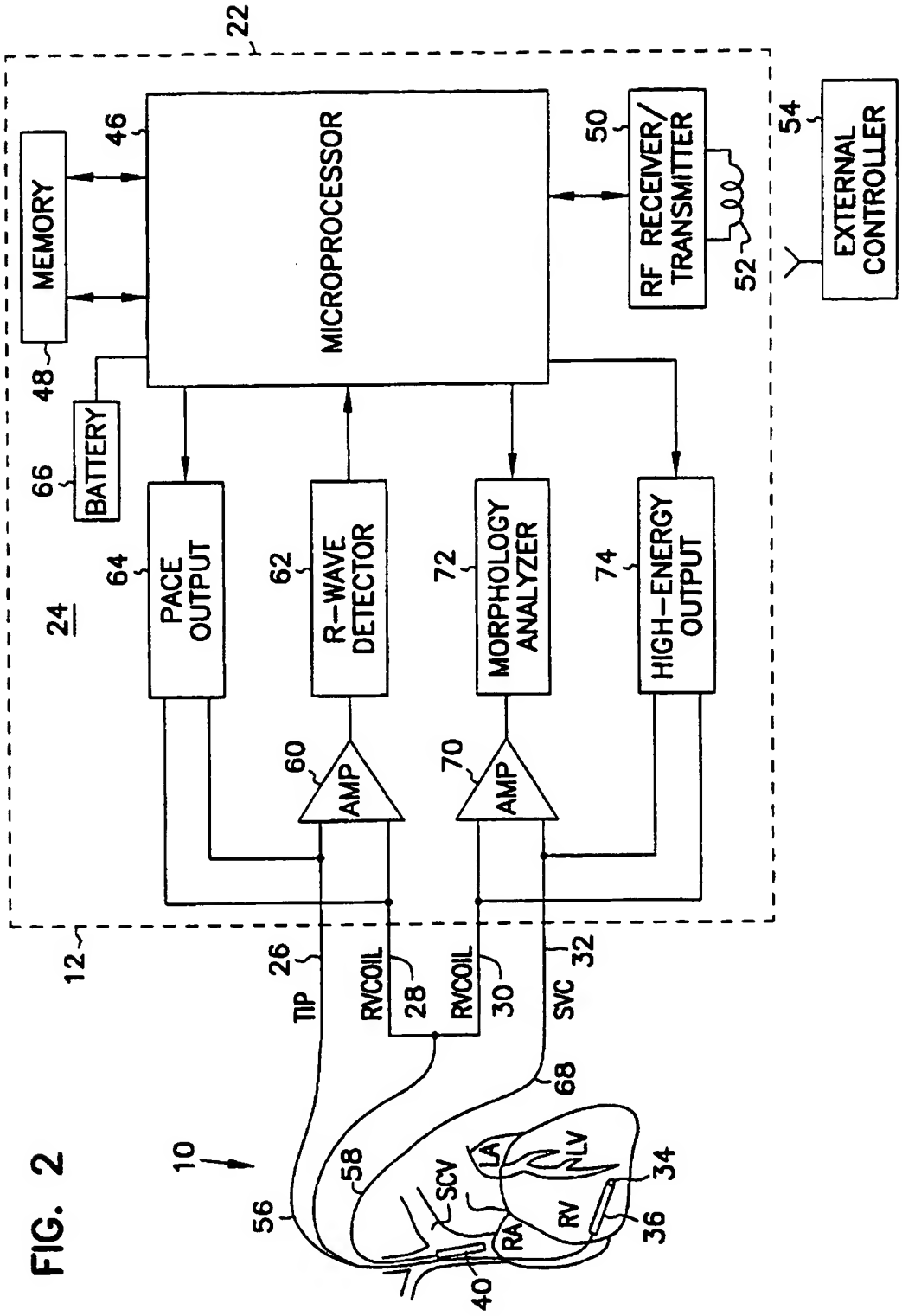

FIG. 2

SUBSTITUTE SHEET (RULE 26)

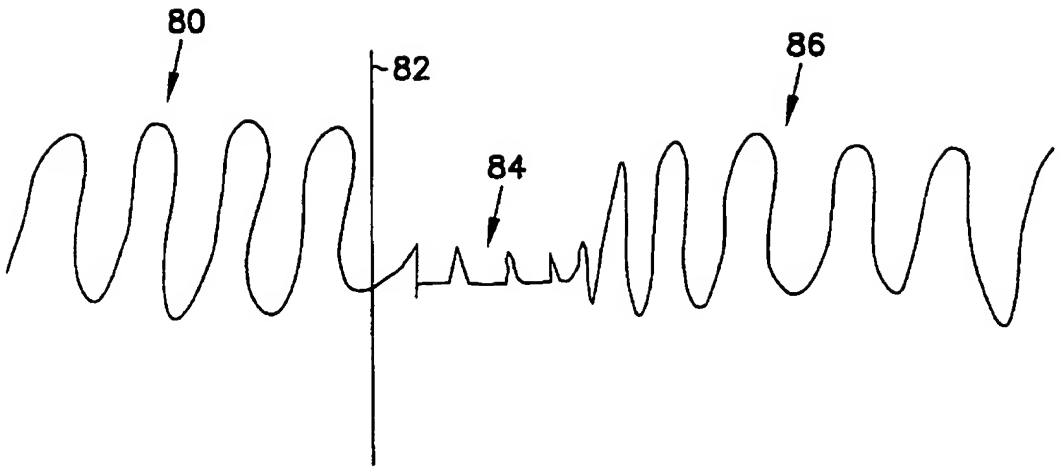

FIG. 3

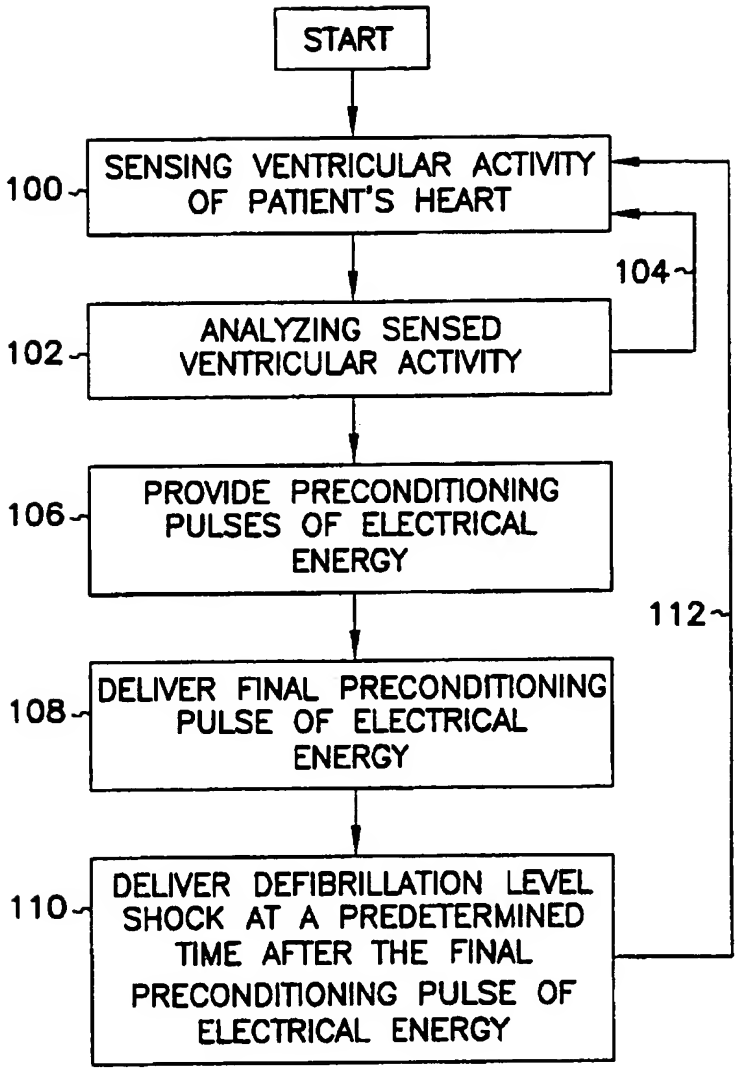

FIG. 4

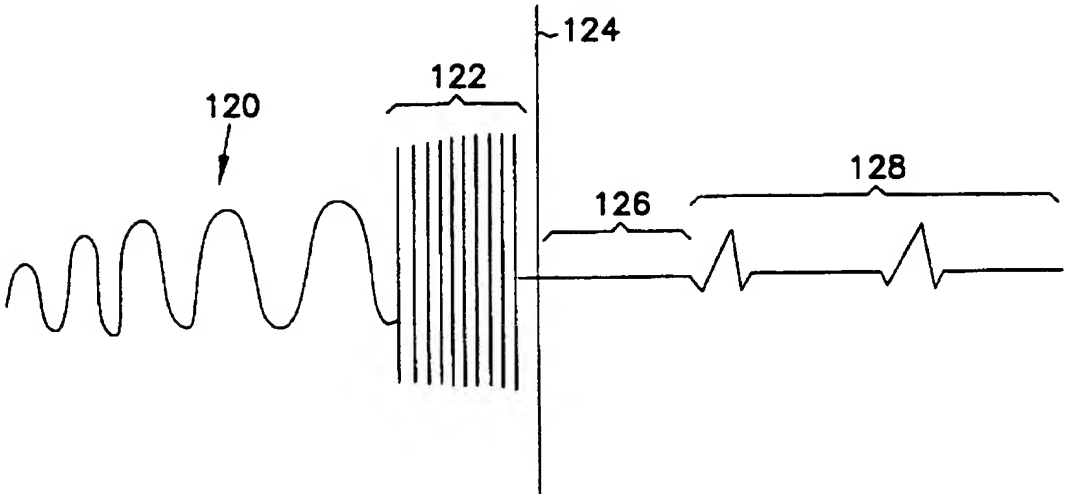

FIG. 5

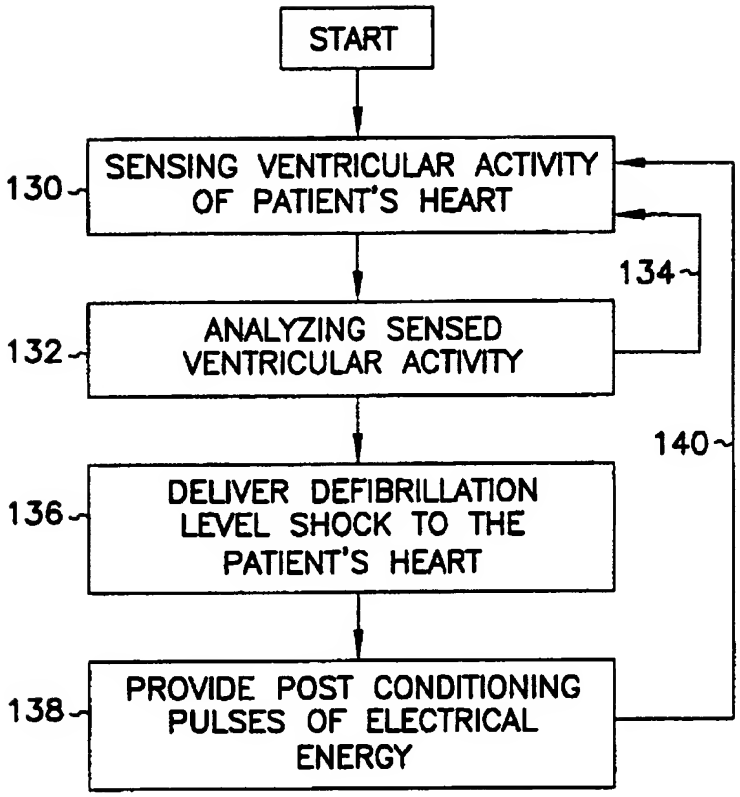

FIG. 6

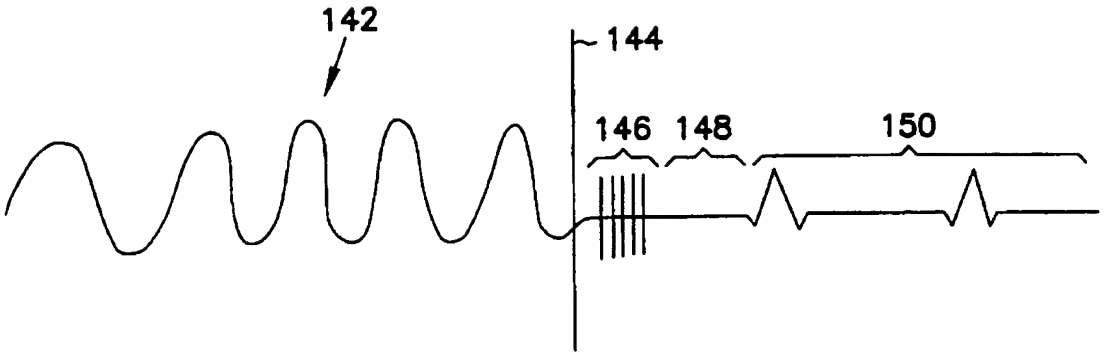

FIG. 7

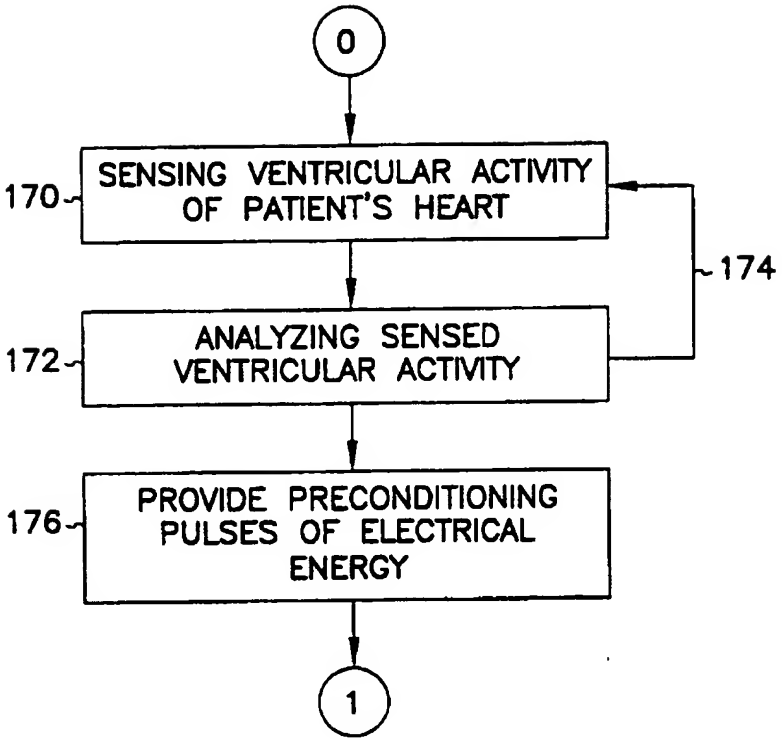

FIG. 8

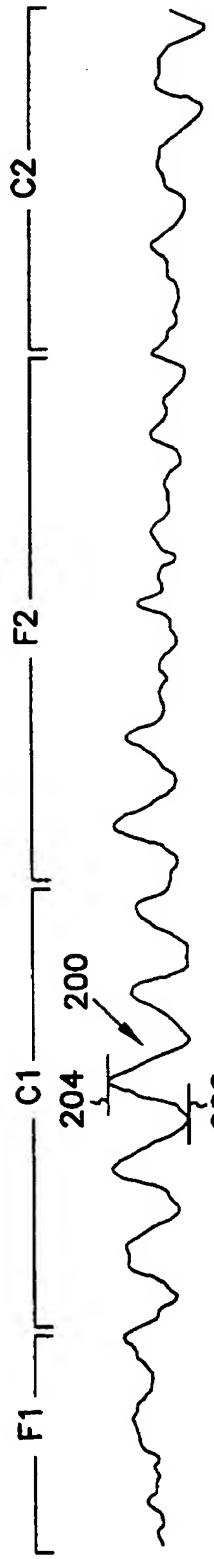

FIG. 9

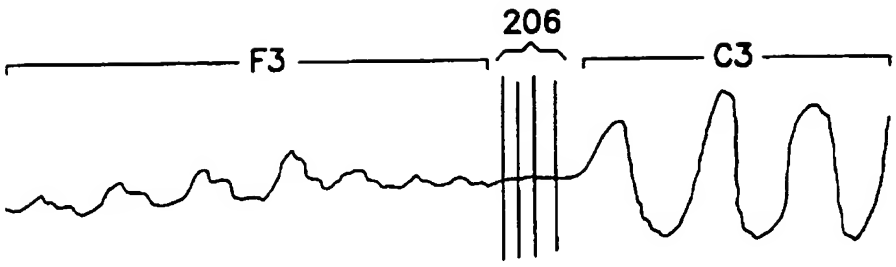

FIG. 10

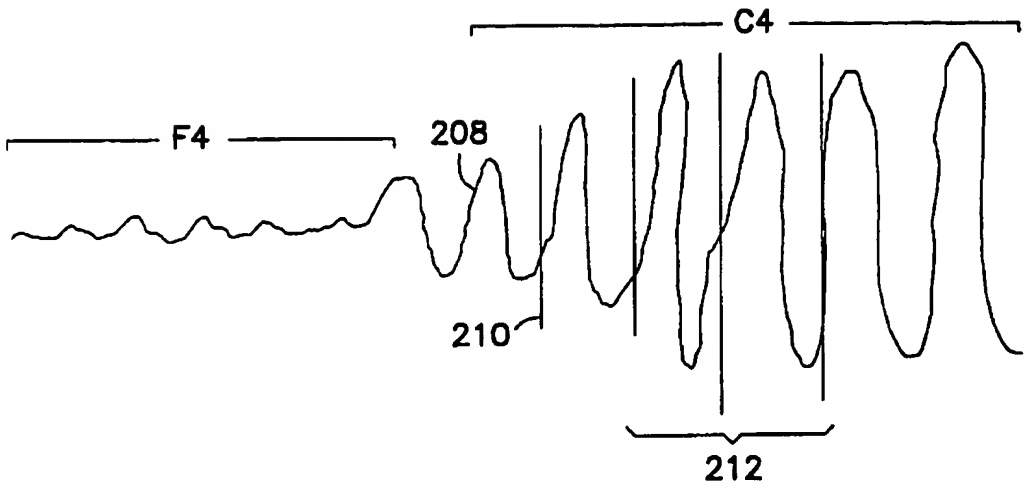

FIG. 11

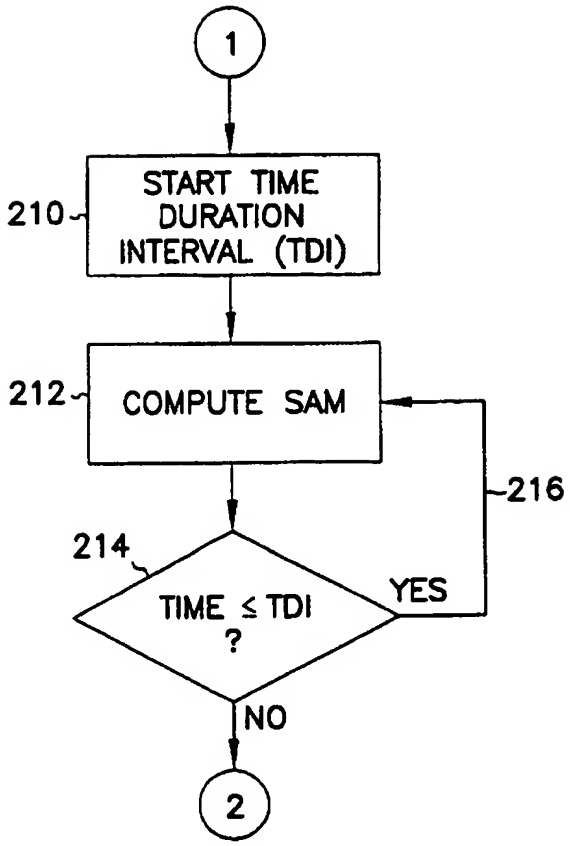

FIG. 12

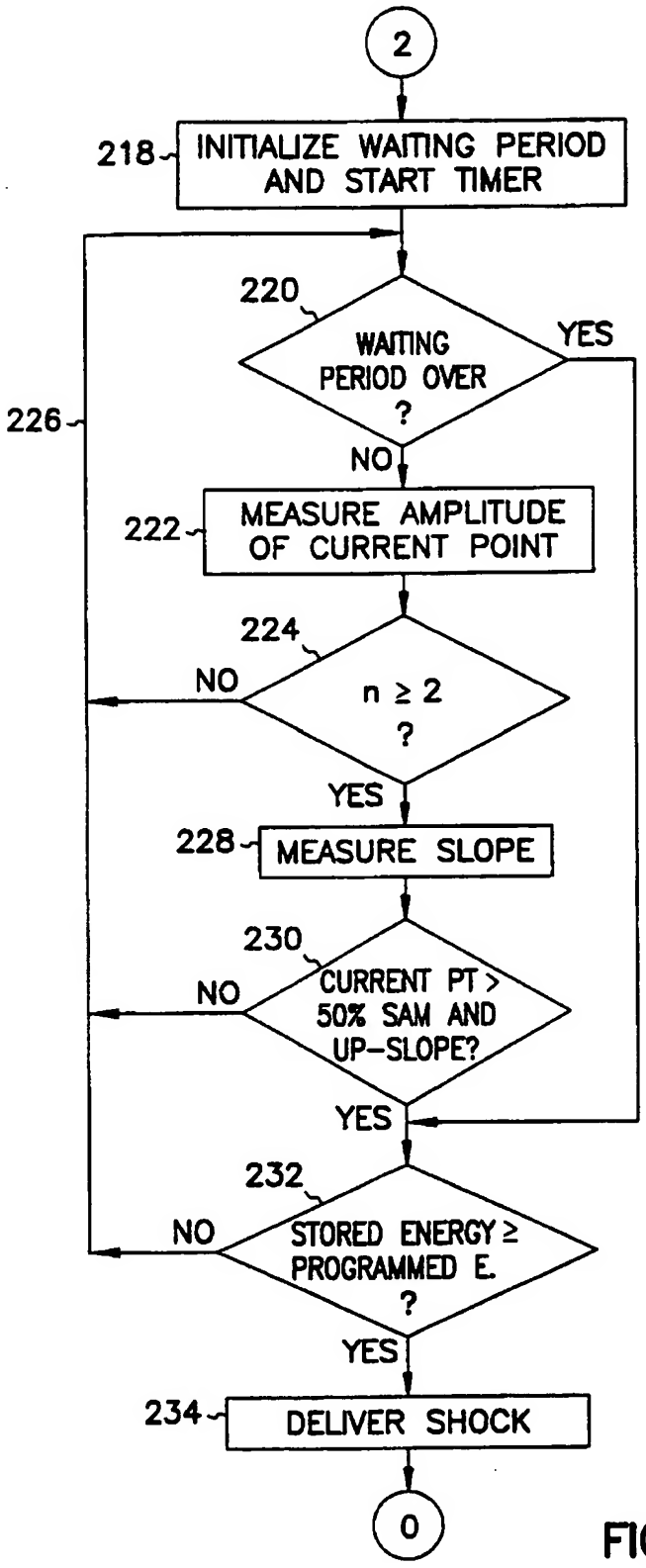

FIG. 13

INTERNATIONAL SEARCH REPORT

Interna. al Application No
PCT/US 98/10741

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N1/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 528 708 A (MIROWSKI MIECZYSLAW) 23 December 1983 see page 4, line 2 - page 6, line 22 see page 10, line 10 - page 14, line 1 see page 15, line 16 - line 20 ---	20-24, 29,40
Y	WO 97 01373 A (MEDTRONIC INC) 16 January 1997 see page 5, line 1 - page 7, line 29 ---	20,21, 23-31, 33-36,40
Y	WO 97 06854 A (CARDIAC PACEMAKERS) 27 February 1997 cited in the application see the whole document --- -/--	20,21, 23-31, 33-36,40

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 August 1998	21.08.98

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Petter, E

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Internal Application No
PCT/US 98/10741

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 674 916 A (VENTRITEX INC) 4 October 1995 see page 3, line 28 - page 5, line 45	20-23, 29,40
A	EP 0 588 125 A (SIEMENS ELEMA AB) 23 March 1994 see the whole document	20,32

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/10741

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-19
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Interna .al Application No
PCT/US 98/10741

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